

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AVANIR PHARMACEUTICALS, INC.,
AVANIR HOLDING COMPANY, AND
CENTER FOR NEUROLOGIC STUDY,

Plaintiffs,

v.

ACTAVIS SOUTH ATLANTIC LLC,
ACTAVIS, INC., PAR PHARMACEUTICAL,
INC., PAR PHARMACEUTICAL
COMPANIES, INC., IMPAX
LABORATORIES, INC., WOCKHARDT,
LTD., WOCKHARDT USA, LLC, WATSON
PHARMACEUTICALS, INC., WATSON
LABORATORIES, INC., AND WATSON
PHARMA, INC.,

Defendants.

C.A. No. 11-704-LPS
(CONSOLIDATED)

JOINT CLAIM CONSTRUCTION CHART

I. Joint Statement

Pursuant to the Court's November 10, 2011 Scheduling Order and the Court's June 7, 2012 modification of the Scheduling Order, Plaintiffs Avanir Pharmaceuticals, Inc., Avanir Holding Company, and Center for Neurologic Study (collectively, "Plaintiffs") and Defendants (1) Actavis South Atlantic LLC and Actavis, Inc.; (2) Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.; (3) Impax Laboratories, Inc.; (4) Wockhardt, Ltd. and Wockhardt USA, LLC; and (5) Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma, Inc. (collectively, "Defendants") identify the disputed terms(s)/phrase(s) of the claims at issue, along with each party's proposed construction of the disputed language with citations to intrinsic evidence in support of their respective proposed constructions.

The patents-in-suit and cited portions from the prosecution histories of the patents-in-suit are attached as Exhibits A – F:

- U.S. Patent No. 7,659,282 (Exhibit A)
- U.S. Patent No. RE 38,115 (Exhibit B)
- Cited portions of the file history of U.S. Patent No. 5,869,927 (Exhibit C)
- Cited portions of the file history of U.S. Patent Application No. 07/896,053 (Exhibit D)
- Cited portions of the file history of PCT Application US94/10771 (Exhibit E)
- Cited portions of the file history of U.S. Patent No. 5,366,980 (Exhibit F)

II. Plaintiffs' Statement

Plaintiffs object to “Defendants’ Statement” as improperly providing argument in support of Defendants’ invalidity claims in direct violation of paragraph 10 of the Scheduling Order (D.I. 32).

III. Defendants' Statement

Defendants’ presentation of a proposed construction should not be construed as a waiver of any argument, including that a claim term, phrase, or element is indefinite or otherwise renders the claim invalid under 35 U.S.C. § 112 or otherwise, and Defendants expressly reserve the right to contest the definiteness of any such terms, phrases, or elements, and the validity of any claim of the patents-in-suit.

Defendants reserve the right to supplement or amend their constructions and evidence. Furthermore, Defendants submit their preliminary constructions and evidence without the benefit of complete discovery. Therefore, Defendants reserve the right to supplement or amend their preliminary constructions and evidence as further evidence is discovered during the course of discovery.

I. Proposed Claim Constructions¹**U.S. PATENT NO. 7,659,282**

<u>Claim</u>	<u>Claim Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>	<u>Intrinsic Evidence</u>
1	"A method for treating pseudobulbar affect or emotional lability"	A method for treating a neurological disorder characterized by intermittent spasmodic outbursts of emotion at inappropriate times or in the absence of any particular provocation	A method for treating the condition known as pseudobulbar affect or emotional lability (also referred to by the terms emotionalism, emotional incontinence, emotional discontrol, excessive emotionalism, and pathological laughing and crying), which is characterized by intermittent spasmodic emotional outbursts at inappropriate times or in the absence of any particular provocation.	Plaintiffs' citations: <ul style="list-style-type: none"> • Col. 1:18-20 • Col. 1:39-43 Defendants' citations: <ul style="list-style-type: none"> • Col. 1:39-47

¹ To the extent that claim terms are used repeatedly throughout a patent, any constructions of such terms carry the same meaning throughout a patent unless otherwise set forth in the accompanying charts.

1	“dextromethorphan in combination with quinidine”	Dextromethorphan and quinidine given in a combined dose, or in separate doses administered substantially simultaneously	Dextromethorphan and quinidine co-administered in combined doses or separate doses.	<p>Plaintiffs’ citations:</p> <ul style="list-style-type: none"> • Col. 2:15-29 • Col. 2:62-67 • Col. 3:28-34 • Col. 4:1-3 • Col. 4:30-39 • Col. 5:30-36 • Col. 6:1-4 • Col. 15:20-22 • Col. 15:39-43 • Col. 20:34-50 • Col. 21:54-62 • Col. 22:1-5 • Col. 25:5-8 • Col. 25:30-26:3 <p>Defendants’ citations:</p> <ul style="list-style-type: none"> • Col. 2:22-29 • Col. 2:34-58 • Col. 12:5-21 • Col. 13:52-14:5 • Col. 14:24-33 • Col. 15:63-16:37 • Col. 15:20-22 • Col. 19:3-7 • Col. 40:10-13 • Col. 41:1-4
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U.S. PATENT NO. RE38,115

<u>Claim</u>	<u>Claim Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>	<u>Intrinsic Evidence</u>
18	"A unit dosage formulation for treatment of chronic or intractable pain"	The preamble is not a claim limitation; needs no construction	[The preamble is a claim limitation.] A unit dosage formulation intended to treat chronic or intractable pain.	Plaintiffs' citations: <ul style="list-style-type: none"> • None. Defendants' citations: <ul style="list-style-type: none"> • Col. 2:34-39 • Col. 2:44-47 • Col. 2:52-56 • Col. 7:13-17 • AVAN-0002144-48 • ParPharma DEX 0017324
18	"a debrisoquin hydroxylase inhibitor"	A cytochrome P-450 2D6 inhibitor, excluding cimetidine	A compound capable of inhibiting the oxidation of dextromethorphan by the liver enzyme debrisoquin hydroxylase.	Plaintiffs' citations: <ul style="list-style-type: none"> • Col. 3:51-4:6 • Col. 4:32-5:2 • Col. 10:64-11:51 • AVAN-0002144-45 Defendants' citations: <ul style="list-style-type: none"> • Col. 2:4-5 • Col. 2: 22-25 • Col. 2:49-52 • Col. 11:28-31
18	"chronic pain"	Long-term pain, i.e., pain lasting three months or longer	Long-term pain resulting from conditions such as stroke, cancer and trauma, as well as neuropathic pain due to deterioration of nerve tissue such as postherpetic neuralgia (PHN) resulting from herpes zoster	Plaintiffs' citations: <ul style="list-style-type: none"> • Col. 2:34-35 • Col. 2:44-47 • AVAN-0002145-46 • ParPharma DEX 0014367 • ParPharma DEX 0017251

<u>Claim</u>	<u>Claim Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>	<u>Intrinsic Evidence</u>
			infection, and diabetic neuropathy resulting from long-time diabetes.	<ul style="list-style-type: none"> • ParPharma DEX 0017253 • ParPharma DEX 0017282 Defendants' citations: <ul style="list-style-type: none"> • Col. 1:37-40 • Col. 2:34-39 • Col. 2:44-47 • Col. 2:52-56 • Col. 7:13-17 • AVAN-0002144-48 • ParPharma DEX 0017324
18	“intractable pain”	Pain that will not respond adequately to conventional medications	Pain which failed to respond to other treatments.	Plaintiffs' citations: <ul style="list-style-type: none"> • Col. 2:26-28 • Col. 2:44-47 • AVAN-0002145-46 • ParPharma DEX 0014367 • ParPharma DEX 0017252-53 • ParPharma DEX 0017272 • ParPharma DEX 0018364 Defendants' citations: <ul style="list-style-type: none"> • Col. 1:37-40 • Col. 2:34-39 • Col. 2:44-47 • Col. 2:52-56 • Col. 7:13-17 • AVAN-0002144-48 • ParPharma DEX 0017324
18	“a combined dosage which renders the	This is not a single claim term and is not amenable to construction;	About 20 mg/day to about 200 mg/day of dextromethorphan or salt	Plaintiffs' citations: <ul style="list-style-type: none"> • Col. 2:26-28 • Col. 2:34-35

<u>Claim</u>	<u>Claim Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>	<u>Intrinsic Evidence</u>
	dextromethorphan therapeutically effective in substantially reducing chronic or intractable pain without causing unacceptable side effects	<p>instead, it should be construed by reference to the individual claim terms contained therein:</p> <p>(1) "a combined dosage;"</p> <p>(2) "which renders;"</p> <p>(3) "the dextromethorphan;"</p> <p>(4) "therapeutically effective;"</p> <p>(5) "in,"</p> <p>(6) "substantially reducing;"</p> <p>(7) "chronic pain,"</p> <p>(8) "intractable pain," and</p> <p>(9) "without causing unacceptable side effects."</p> <p>Plaintiffs assert that except for "chronic pain" and "intractable pain" (as defined above), each of these terms needs no construction and has its ordinary meaning.</p> <p>To the extent that the Court finds that construction of the entire phrase is necessary, Plaintiffs propose that the meaning is the sum of the individual claim terms.</p> <p>Defendants' have refused repeated requests to propose constructions for, or to even discuss, the terms: "which renders;" "the dextromethorphan;" "therapeutically effective;" "in;" "substantially reducing;" and "without causing</p>	<p>thereof and 50 mg/day to 300 mg/day of the debrisoquin hydroxylase inhibitor (DHI) quinidine for treatment of chronic or intractable pain. Dosages of other DHIs will vary with the DHI, and should be determined on an individual basis using the protocol described in Example 4.</p> <p>To the extent Defendants' construction is not adopted and "substantially reducing chronic or intractable pain" needs further construction, it is indefinite and/or does not otherwise satisfy the requirements of 35 U.S.C. § 112.</p> <p>To the extent Defendants' construction is not adopted and "without causing unacceptable side effects" needs further construction, it is indefinite and/or does not otherwise satisfy the requirements of 35 U.S.C. § 112.</p> <p>Defendants object to Plaintiffs' identification of "the individual claim terms" in this claim phrase as new terms. By dividing one claim phrase into nine, Plaintiffs improperly identified seven new claim terms. The Scheduling Order</p>	<ul style="list-style-type: none"> • Col. 2:44-47 • AVAN-0002145-46 • ParPharma DEX 0014367 • ParPharma DEX 0017251-53 • ParPharma DEX 0017272 • ParPharma DEX 0017282 • ParPharma DEX 0018364 <p>Defendants' citations:</p> <ul style="list-style-type: none"> • Col. 4:9-14 • Col. 4:23-32 • Col. 4:67-5:2 • Col. 6:37-40 • Col. 14:43-48 • Col. 14:65-67 • Col. 15:6-8 • Col. 15:48-55 • Col. 16:13-15

<u>Claim</u>	<u>Claim Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>	<u>Intrinsic Evidence</u>
		<p>unacceptable side effects.” Defendants' refusal should be deemed a waiver, precluding Defendants from subsequently offering any competing constructions of these terms.</p> <p>Defendants have also refused to reveal their position on whether these terms need construction. Defendants should similarly be precluded from offering any subsequent arguments regarding whether these terms need construction.</p>	<p>(D.I. 13) allows only identification of claim terms and phrases “that [the parties] believe need construction” Because Plaintiffs state that these terms “need[] no construction,” the terms are not properly identified. Also, Plaintiffs identified these terms for the first time on July 13, 2012, long after the Court’s June 20, 2012 deadline for identifying claim terms and phrases for construction.</p> <p>Plaintiffs’ assertion that “Defendants have refused repeated requests to propose constructions for, or even discuss, the [new] terms” is inaccurate, given that the parties have exchanged numerous letters and held two meet-and-confer teleconferences that addressed the new terms.</p> <p>Plaintiffs have waived any right to assert these new terms because they were proposed after the deadline.</p>	

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